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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,478

02/23/2004

Paul Hafner

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,478

Applicant(s)

HAEFNER, PAUL

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 30-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Diack et al. (US Re. 30,750, hereinafter "Diack").
3. In regards to claims 1 and 30, Diack discloses detecting a composite electrical signal and separating a signal from the composite signal using source separation (Fig. 14, element 110 and col. 18, line 66), receiving information associated with a non-electrophysiological source (Fig. 14, element 122), and verifying that the separated signal is a cardiac signal, e.g. a "normal" cardiac signal, using both signals (Table 1). Further, the composite signal is acquired at a subcutaneous non-intrathoracic location (col. 26, line 17).
4. In regards to claims 4, 7, 8, and 10, the non-electrophysiological cardiac source comprises acoustic information, blood flow information, pulse pressure information, and impedance information (col. 2, line 26).
5. In regards to claims 16 and 17, a cardiac condition is detected using a correlation between the signals (abstract and Table 1).

6. In regards to claims 18, 19 and 34-36, a cardiac arrhythmia is detected and treated (abstract and Table 1).
7. In regards to claim 31, because the two signals are "and-ed", the two signals are time-correlated.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-19 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yomtov et al. (US 5,388,578, hereinafter "Yomtov") in view of Joo et al. (US 2005/0240234, hereinafter "Joo"). Yomtov discloses the essential features of the claimed invention including the following:

10. In regards to claims 1, 4-10, and 30, Yomtov discloses detecting a composite electrical signal at a subcutaneous non-intrathoracic location (Fig. 1), separating a signal from the composite signal and verifying that the separated signal is a cardiac signal using a second cardiac source signal (element 96; col. 17, line 40; and Figs. 8A and 8B). Yomtov does not disclose that the second cardiac source signal is a non-electrophysiological signal comprising acoustic emission information, blood flow information, pulse pressure information, pulse oximetry information or transthoracic impedance information. Joo teaches of utilizing both an electrophysiological and non-

electrophysiological signal comprising acoustic emission information, blood flow information, pulse pressure information, pulse oximetry information or transthoracic impedance information to confirm a cardiac pulse (abstract and par. 0104) to provide redundancy in recognizing a cardiac pulse using conventional equivalent transduction means susceptible to different forms of noise, thusly providing highly accurate arrhythmia recognition. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Yomtov's invention by utilizing both an electrophysiological and non-electrophysiological signal to confirm a cardiac pulse to provide the predictable result of providing redundancy in recognizing a cardiac pulse using conventional equivalent transduction means susceptible to different forms of noise, thusly providing highly accurate arrhythmia recognition.

11. In regards to claims 2, 3, 11, and 31-33, Yomtov discloses that the second signal is used to define a detection window comprising a QRS complex through correlation (col. 14, line 24).

12. In regards to claims 12 and 13, a peak separation is determined and used to identify a cardiac signal (col. 15 line 23).

13. In regards to claims 16, 17, 18, 34, and 36, a cardiac condition is detected using a correlation between the two signals (see above) wherein the condition is arrhythmia (col. 3, line 23).

14. In regards to claims 19 and 35, the arrhythmia is treated (col. 8, line 43).

Because defibrillation protection circuitry is provided, a defibrillator must be present, whether part of device 32, or external to device 32.

15. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yomtov in view of Joo, as applied to claim 1 above, and further in view of Wells (US 2003/0032889 hereinafter "Wells"). The modified invention of Yomtov discloses the essential features of the claimed invention except for separating signals using blind source separation and independent component analysis. Wells teaches of identifying constituent signals using blind source separation and independent component analysis (par. 0007) to separate signals where little is know of their individual contributions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Yomtov's invention by identifying constituent signals using blind source separation and independent component analysis to provide the predictable result of separating signals where little is know of their individual contributions.

Response to Arguments

16. Applicant's arguments filed 9/13/2007 have been fully considered but they are not persuasive. Applicant argued that neither Diack nor Yomtov disclose separating signals using source separation because the filtering technique taught by Diack and the R-wave detector/beat separation taught by Yomtov do not separate by source origins, as a artisan of ordinary skill would understand "source separation". However, the Examiner takes the position that the filtering technique taught by Diack and the R-wave detector/beat separation taught by Yomtov are "source separation" because they separate the desired source signal (the clean ECG signal, and an individual beat signal,

respectively) from undesired sources (e.g., skeletal muscle noise, other beats, etc.).

Regardless of whether this is performed via manipulation of frequencies or time windowing, the desired source signal is separated from the noise signal. This is a separation of a signal according to its respective source origin. The Examiner is not importing into the claims from the disclosure further limitation to this term.

17. Applicant further argued that Diack does not disclose using any of the sensed signals to verify the other signal. As described above, Diack discloses at, e.g., Table I that the separated ("EKG") and non-electrophysiological ("Respir. Sensor") signals are used to verify that the separated signal is a "normal cardiac signal", "cardiac signal requiring defibrillation", or "cardiac signal requiring pacing". In other words, regardless of whether the signals are used to verify whether the separated signal is a cardiac (versus non-cardiac) signal, the two signals are used to determine whether the signal is a "normal cardiac signal" (versus an abnormal cardiac signal). Since the normal and abnormal cardiac signals are examples of "a cardiac signal", as claimed, Diack anticipates the claimed subject matter.

18. Applicant further argued that Yomtov fails to disclose verifying a separated signal is a cardiac signal using a separated signal and second signal because it is unclear which of Yomtov's signals are the separated signal, and Yomtov allegedly verifies each channel independently of the other using thresholds. Since the signals in both channels are separated by beat, either or both channels are the "separated signal" that the claim language requires. Additionally, regardless of Yomtov's discussion of thresholds or channel switching at the top of column 17, the cited passage (starting at line 40 of

column 17) very clearly indicates that both signals from the first and second channels are used to verify a beat is a valid heart signal. Joo is relied upon merely for the teaching that non-electrophysiological signals can also be used, instead of the electrophysiological signals of Yomtov.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

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10/24/07

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GEORGE R. EVANISKO
PRIMARY EXAMINER

10/25/07